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04/07/23 • BIG PHARMA › NEWS

Pfizer's RSV Vaccine for Older Adults Linked to Guillain-Barré Syndrome, But Drugmaker Says It's 'Safe'

People who receive Pfizer's respiratory syncytial virus vaccine should be monitored for Guillain-Barré syndrome, according to the authors of a Pfizer-funded study published this week in the New England Journal of Medicine.

By Brenda Baletti, Ph.D.

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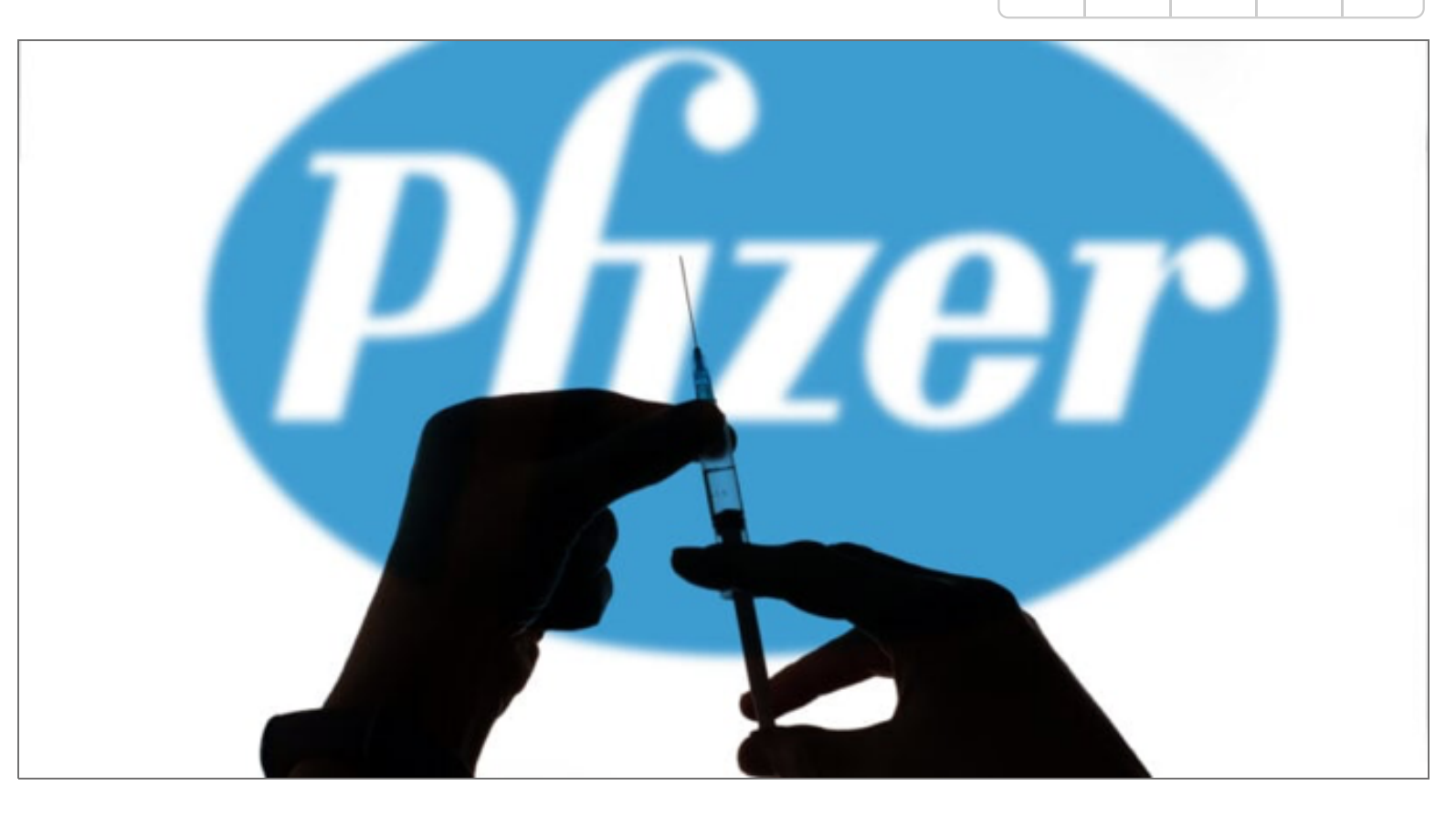

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People who receive Pfizer's respiratory syncytial virus (RSV) vaccine should be monitored for Guillain-Barré syndrome, according to the authors of a Pfizer-funded study published this week in the New England Journal of Medicine (NEJM).

The paper — one of several published Wednesday reporting interim analyses for Pfizer's phase 3 clinical trials for the RSV vaccine — concluded the vaccine was effective in preventing RSV in adults age 60 and over "without evident safety concerns."

But that same article also flagged Guillain-Barré syndrome as a safety concern moving forward with the vaccine.

"If RSVpreF vaccine [Pfizer's RSV vaccine] is approved and recommended, these adverse events warrant close monitoring in future studies and with real-world data and post-marketing surveillance," the authors of the NEJM study said.

The U.S. Food and Drug Administration (FDA) is expected to approve Pfizer's RSV vaccine for older adults in May.

Safe and effective?

Guillain-Barré syndrome is a rare disorder in which the body's immune system attacks its own nerves. Symptoms can range from brief weakness to paralysis.

The FDA asked Pfizer to include the condition as an "important potential risk" of the vaccine and to develop a safety study to monitor for potential cases if the shot is approved, CNBC reported.

When the FDA vaccine advisory panel met in February to review Pfizer's data pre-publication, there was substantial disagreement about the data on safety and effectiveness, although the majority of the committee voted to recommend the vaccine for approval.

Four of 12 committee members voted that the safety data was not adequate for approval — and one abstained — because of their concerns with the Guillain-Barré cases.

Four committee members also voted the evidence of vaccine effectiveness was not adequate for approval, while seven said it was and one member abstained.

In the NEJM study, one person developed Guillain-Barré syndrome and another developed Miller Fisher syndrome, a subset of Guillain-Barré. The symptoms appeared six and seven days post-vaccination, respectively.

The person with Miller Fisher syndrome recovered. The person diagnosed with Guillain-Barré continues to suffer from loss of motor function.

CNBC reported:

> "In the New England Journal of Medicine article, the scientists said the two cases occurred in patients who were in an age group that has an increased risk of developing Guillain-Barré. Potential factors other than the vaccine also could have caused the individuals to develop the syndrome, they added.
>
> "But the FDA said the agency views the Guillain-Barré cases as possibly related to the vaccine because the patients developed the syndrome shortly after receiving the shot, according to briefing documents published in February.
>
> "Pfizer concluded that the cases were unrelated, and the clinical trial's data monitoring committee did not identify any safety concerns with the vaccine."

Dr. Hana El Sahly, the FDA committee chair and professor of molecular virology and microbiology and infectious diseases at the Baylor College of Medicine, said Guillain-Barré has an incidence of about 1 in 100,000 among people ages 60 and older. But in the vaccine trial, the rate was closer to 1 in 9,000, which is significantly higher.

"It's significant in terms of incidence," she said. The FDA advisors told Pfizer that safety monitoring for Guillain-Barré after FDA approval "would be crucial," CNBC reported.

There is currently no vaccine approved to prevent RSV, a lower respiratory disease that is one of the most common causes of childhood cold-like illness and was first discovered in humans in 1956.

The illness is mild for most people.

In children under age 5, RSV causes 58,000 to 80,000 hospitalizations per year and 100 to 300 deaths.

In adults ages 65 and older, RSV causes 6,000 to 10,000 deaths and 60,000 to 160,000 hospitalizations per year, according to the Centers for Disease Control and Prevention.

Research shows the virus originated in monkeys housed in a Maryland facility where they were used to conduct polio vaccine research.

Brian Hooker, Ph.D., P.E., chief scientific officer for Children's Health Defense (CHD), told The Defender:

> "I find it ironic that Pfizer is creating a vaccine for RSV, an illness that was created due to the development of the polio vaccine. It seems like vaccine manufacturers are paid to prevent diseases that they already created.
>
> "The incidence of Guillain-Barré is very troubling and although many patients recover, there is nerve damage associated with it leading to permanent weakness, numbness and fatigue."

The NEJM study reported that the vaccine was 86% effective at preventing lower respiratory tract illness with three or more symptoms, and 66% effective at preventing the illness with two or more symptoms, among adults over age 60.

The study determined there were not enough cases of severe RSV-associated lower respiratory tract illness — meaning cases needing hospitalization or ventilation or extra oxygen — to determine whether the vaccine was effective for those cases, CNN reported.

RSV vaccines for pregnant women failed to meet major goal in trials

Pfizer is also seeking FDA approval for its vaccine to protect infants from RSV by vaccinating pregnant mothers.

However, in the interim data on clinical trials, also published Wednesday in the NEJM, the vaccine failed to meet one of its two main goals.

Last year, Pfizer reported that its vaccine was highly effective at protecting newborns from RSV. The drugmaker also sought rapid FDA approval for the vaccine for pregnant mothers.

The FDA is expected to decide by August.

According to the study published Wednesday, the vaccine was 82% effective in preventing severe lower respiratory tract illness — such as very low oxygen levels or need for ventilator support — in infants in the first 90 days of life, but that dropped to 69% efficacy up to 180 days after a baby is born.

But the vaccine failed to meet its second big goal: reducing non-severe RSV-associated lower respiratory illness in infants.

The study enrolled 7,128 women — half received the RSV vaccine and half received the placebo.

Severe illness occurred within three months in six infants whose mothers received the vaccine, compared with 33 infants from the placebo group who contracted serious RSV infections.

The company evaluated 3,570 infants as part of the study, Reuters reported.

Big Pharma's race for the RSV vaccine

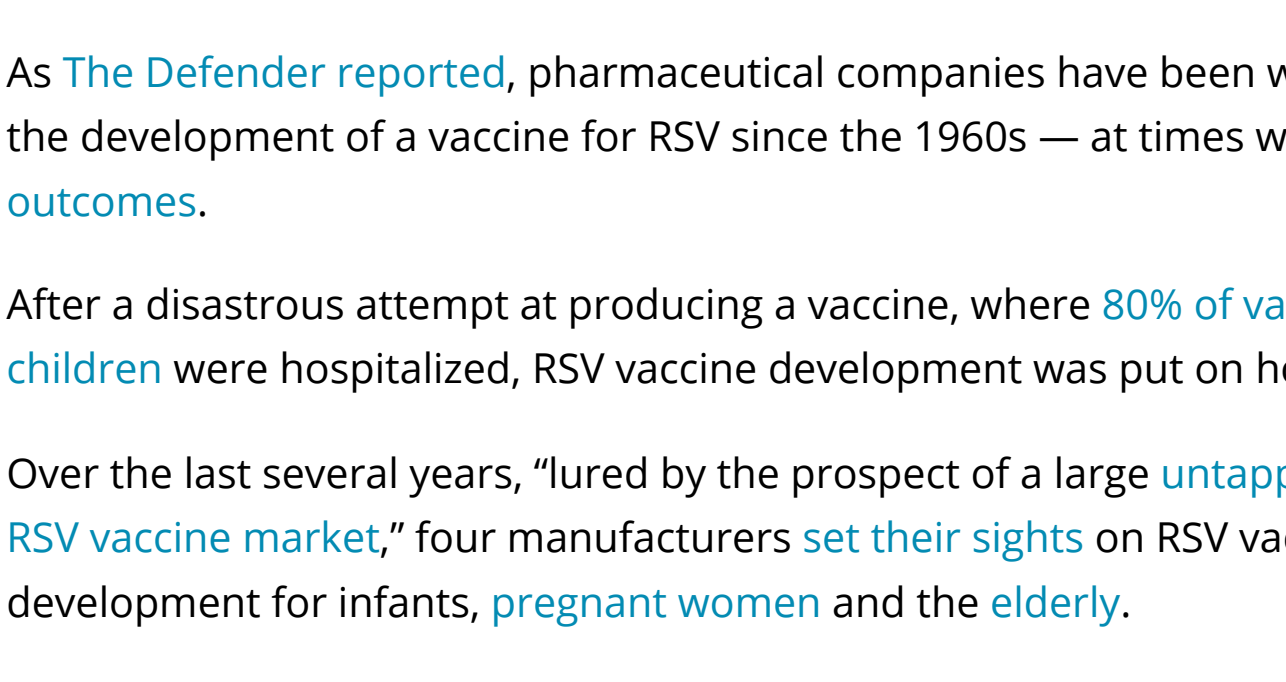
The RSV virus causes annual outbreaks of respiratory illnesses in all age groups, typically during the fall, winter and spring in most regions of the U.S. It has existed for decades and doesn't usually spark alarm.

But RSV made headlines last fall as part of a "tripledemic" — COVID-19, flu and RSV — scare, just as these new RSV products were preparing to come on the market.

Robert F. Kennedy, Jr., CHD chairman-on-leave, said at the time, "fear sells," tweeting:

Robert F. Kennedy Jr
@RobertKennedyJr · Follow

While influenza, RSV and COVID-19 can be problematic and dangerous for certain high-risk individuals, the overall risks associated with them are negligible for most — but "fear sells" and for Big Pharma, it sells more vaccines.



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As The Defender reported, pharmaceutical companies have been working on the development of a vaccine for RSV since the 1960s — at times with deadly outcomes.

After a disastrous attempt at producing a vaccine, where 80% of vaccinated children were hospitalized, RSV vaccine development was put on hold.

Over the last several years, "lured by the prospect of a large untapped global RSV vaccine market," four manufacturers set their sights on RSV vaccine development for infants, pregnant women and the elderly.

Initially, Johnson & Johnson and Bavarian Nordic also were developing RSV vaccines, but the former dropped out of the race last month and Bavarian Nordic's clinical trials are in progress.

That leaves Pfizer and GlaxoSmithKline (GSK), who have been in a tight race to be the first Big Pharma player to tap into the RSV vaccine market, which is estimated to be over $5 billion and could exceed $10 billion by 2030, Reuters reported last month.

Both companies have RSV vaccines under regulatory review with the FDA.

The FDA advisory committee voted unanimously in favor of GSK's vaccine's effectiveness in preventing lower respiratory tract disease caused by RSV in adults aged 60 and above, and voted 10 to 2 for its safety last month, based on interim data presented last October, Reuters reported.

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Brenda Baletti, Ph.D.

Brenda Baletti Ph.D. is a reporter for The Defender. She wrote and taught about capitalism and politics for 10 years in the writing program at Duke University. She holds a Ph.D. in human geography from the University of North Carolina at Chapel Hill and a master's from the University of Texas at Austin.

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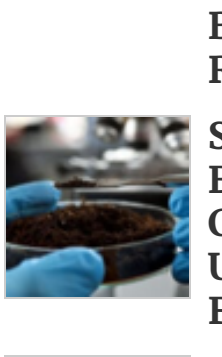

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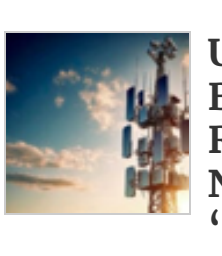

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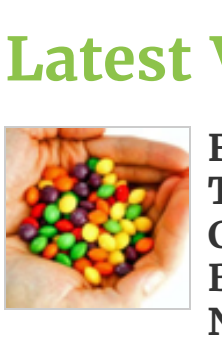

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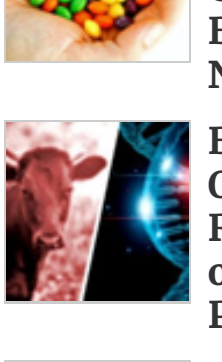

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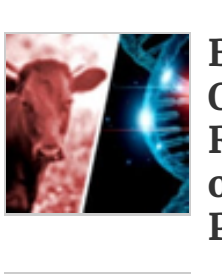

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Roxy
11 days ago

GBS is another name for Polio, which is another name for paralysis. Both have the same cause - poison. Poison from the vaccine or poison from spraying DDT on everyone and everything imaginable in the 1940s/50s. Not from an imaginary virus flying from person to person. So when we hear people got "polio" from the alleged live virus vaccines, is it really "polio" or is it GBS? How would one know the difference, when they are both technically paralysis?

15 0 Reply • Share ›

RHE9 → Roxy
11 days ago edited

Yes, the graphs correlating DDT exposure and "polio outbreaks" is shocking...
***And prior to Salk and Sabin vaccines being marketed, meningitis and Coxsackie were also labelled "polio", hence "polio" cases were marketed as declining because they changed the definition of "polio"... They also changed the diagnosis for polio, thereby making it appear that the Trojan Horse "miracle" vaccine was responsible... Years on, how many millions developed cancer from the SV-40 contamination of the polio vaccine?!

7 0 Reply • Share ›

CATRYNA49 → Roxy
11 days ago

You are so right. They have changed the name of this disease so many times and the parameters of identification. It has been criminal for decades; actually the whole idea of vaccines has been the bane of mankind for over 200 years.

4 0 Reply • Share ›

Peter van der Stam → CATRYNA49
10 days ago

If they didn't change the name on a regular basis, they would NOT be able to sell as much.
Medical Mafia.

1 0 Reply • Share ›

BarbaraCharis
11 days ago

Sorry! I don't buy Safe & Effective. Anything, particularly toxic matter, injected into the bloodstream will overwhelm and destroy the Immune System..not strengthen it. The only thing that belongs in the bloodstream are nutrients...and this is what strengthens the immune system.

11 0 Reply • Share ›

Ricky Ricardo → BarbaraCharis
9 days ago

Injecting SYNTHETIC substances into the human body? I don't think so! In the 70's, people were saying that we live in a plastic world with plastic people...nothing was real and genuine anymore. That's never been truer than it is today. The evil psychopaths who play God, hate all things natural and are attempting to recreate everything that is natural - synthetically; from "food", to "vaccines", to plants; and now, they are attempting to recreate humans! Their agenda is all laid out on the WEF website - in plain site!

2 0 Reply • Share ›

CateRose → Ricky Ricardo
9 days ago

What's really scary is we can't escape this if it is allowed to play all the way out. I think they have plans for the entire planet. Would it be better to leave USA? Is there someplace where people are smart enough and strong enough to resist this?

1 0 Reply • Share ›

Ricky Ricardo → CateRose
9 days ago

What's been going on for many years, long before convid, will continue until the agendas are fulfilled. I don't like to be the voice of "gloom and doom"; but, I've been paying close attention for well over a decade and I don't see anything even slowing down this speeding freight train (without a braking system). The Digital ID's and Digital Currency (total surveillance and total control), is coming within the next 2-3 years. I would welcome someone to prove me wrong!

0 0 Reply • Share ›

notaluvvie
11 days ago

Pfizer is one of the biggest criminal organsastions on the planet and it's never shutdown.One can only assume its pay-offs to politicians and public servants and the various "industry" members are huge. They don't even have to be direct cash. For example, daughter wants to study at The Sorbonne? Done. Son wants a new Ferrari? Done.Pfizer et al are drug pushers, they get the sheeple hooked on one "wonder drug" paid for by the taxpayer and the next thing the sheeple know they are on booster number 7 in fear of their lives not to use the experimental drugs.

10 0 Reply • Share ›

BarbaraCharis → notaluvvie
9 days ago

Attribute the success of this monstrous drug industry to our own
Congress giving them a monopoly to destroy people without liabilty for injury or death with the passage of The National Childhood Vaccine Injury Act of 1986...the industry would have gone out of business, because from all the multi-million dollar lawsuits it faced. Now our elected Congress is still in the act - backing up a drug industry that has harmed our country immensely.

1 0 Reply • Share ›

Ricky Ricardo → notaluvvie
9 days ago

"Just say NO" to Big Pharma's drugs! They're all evil and corrupt DRUG PUSHERS - right down to the doctors and pharmacies.

0 0 Reply • Share ›

Bry
11 days ago

Hard to believe people are that stupid to take a jab after covid.

4 0 Reply • Share ›

annemat → Bry
11 days ago

Yet they will, you cannot fix stupid!

1 0 Reply • Share ›

Peter van der Stam → annemat
10 days ago

They might come up with a vaccine to just get the stupidity out of the humans.
OK, they have to die first.

0 0 Reply • Share ›

CATRYNA49
11 days ago

Duh. All vaccines are capable of nerve damage.

4 0 Reply • Share ›

annemat
11 days ago edited

People should be monitored for Guillain Barre syndrome following the RSV vaccine? well good luck with that in the U.K and our world beating NHS. I have a friend who has had severe neurological symptoms for over a year following her 3rd covid injection and she is still unable to access a NHS neurologist until December'23/January'24

3 0 Reply • Share ›

CateRose
9 days ago

One more thing: I notice more and more vaccines target older citizens (besides the young). And with all the vile things said by some of the "globalists" regarding "usefulness" of citizens, I find it very scary for older citizens to get their injections they promote. I've heard many of these "globalists" saying stuff like "people should not live past 70", etc., and then encourage Euthanasia.

So, a person pays their taxes their whole life and when they retire they are suddenly "useless eaters". So, how do they get rid of people they deem useless? Well, more vaccines for one thing.

We need to stop associating Human Beings with "how useful" they are to society, because we know they are talking money-wise. Everything has a huge $$ sign now days.

2 0 Reply • Share ›

jerry wrider
11 days ago

Trust GOD? Trust Big Pharma? Easy enough to answer.

2 0 Reply • Share ›

Ricky Ricardo
9 days ago edited

These discussions are futile! The world has gone insane - and stupid. **My God-given immune system PROTECTS me** from **ALL** the viruses that Big Pharma is making **HUNDREDS of BILLIONS** of $$$ "**treating**". In the meantime; the "treatments" are sickening and killing people. I'm afraid that soon; getting out of bed in the morning and putting your socks on, will become Rocket Science for the masses! If you're **not sick** why would you ever need Big Pharma's help, to make you **not sick**? Humanity is so easily conned. There never was a PANDEMIC! If there had been a pandemic, I and millions of other healthy people certainly would have noticed! We all would have been sick and dead! Isn't that what "pandemics" are supposed to do? Millions more will die from the BIOWEAPON that they call mRNA! The mRNA is altering human DNA. Research Reverse Transcriptase. Never mind...it's becoming more and more difficult to find the truth. I'll do it for you! You don't need to read past the definition at the top. It's all Big Pharma propaganda. https://www.rxlist.com/reve...

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Carrie Lavine
9 days ago edited

As Pediatric Dr Brian Hooker said-The RSV vaccine developed..to fix the RSV caused from the development of the Polio vaccine..&monkey virus in a Maryland lab.(At least this fact escaped from a lab.Vaccines are incapable of "preventing diseases..do NOT give immunity-antibodies via vaccine r generated via brain toxins injected into the blood system&Central Nervous System&cause either Increased Susceptibility to infection said to prevent or cause Chronic Illnesses..resurect diseases once not epidemic-Guilllian Barr-called by CDC "The New Polio"that causes many times Paralysis&sometimes Fatal.The Endless human experimentation for Mass Profit&cultivating diseases.RSV is not genetic..its not chronic..it

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